

51. (New) The method as set forth in claim 50, wherein the probe is a microdialysis probe.
52. (New) The method as set forth in claim 46, wherein the step of accessing body fluids further comprises the step of routing a sensor from a point outside the patient body, through the self-closing diaphragm and into the tube arrangement.
53. (New) The method as set forth in claim 52, wherein the shaft is made of a metallic material and acts as a reference or counter electrode for the sensor.
54. (New) The method as set forth in claim 52, wherein the sensor remains at the test site for continuous testing.
55. (New) The method as set forth in claim 52, wherein body fluid is aspirated to the test site, the sensor being located at the test site.

REMARKS

I. Rejections Under 35 U.S.C. § 102

Claims 1, 22, 23, and 40 were rejected under 35 U.S.C. § 102(b) as being anticipated by Gumbrecht et al., Polanyi, or Blanco et al. Claim 1 has been canceled and claims 22 and 23 have been amended.

A. Independent Claims 22, 23 And 40 Are Not Anticipated By Gumbrecht, Polanyi, And Blanco.

It is respectfully submitted that independent claims 22, 23 and 40 are not anticipated by Gumbrecht, Polanyi, and Blanco. In order for a reference to anticipate a claim, the reference must contain each and every claimed element. The applicants' invention is a method of analyzing or testing body fluids wherein a port body is implanted in a patient's body in such a manner that a portion of the port body extends through the patient's skin and is exposed, i.e., lies outside the patient's body.

Gumbrecht, Polanyi, and Blanco each fail to disclose every aspect of the claimed invention. For example, Gumbrecht and Polanyi teach a catheter that is simply inserted into a

patient's blood vessel. Neither of these references teaches implanting a port body into the body of the patient. Thus, Gumbrecht and Polanyi do not anticipate the claims.

Blanco teaches "[a]n implantable blood monitoring and medication administering system . . . which is implantable beneath the skin." *Blanco, Abstract. (emphasis added)* Further, "all steps [of the Blanco method] take place totally within the body." *Blanco, col. 3, ll. 20-21*. Thus, it is clear that Blanco's device is located completely within a patient's body, under the skin. This is in contrast to the applicants' invention as claimed, wherein the port body has a portion extending through the skin. Therefore, Blanco does not anticipate the claims.

II. Rejections Under 35 U.S.C. § 103

Claims 2-9, 11, and 19-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gumbrecht et al. or Polanyi, in view of Blanco, et al. Claims 2-9, 11, and 19-21 have been canceled and independent claims 22 and 23 have been amended.

A. Claims 22-45 Are Not Made Obvious By Gumbrecht, Polanyi, And Blanco.

It is respectfully submitted that claims 22-45 are not made obvious by Gumbrecht, Polanyi, and Blanco. In order for a combination of references to make obvious a claim, that combination of references must teach or suggest each and every claimed element. As claimed in independent claims 22, 23 and 40, the applicants' invention is a method of analyzing or testing body fluids wherein a port body is implanted in a patient's body in such a manner that a portion of the port body extends through the skin so it is exposed or lies outside the patient's body.

Gumbrecht and Polanyi "disclose a system for the examination of a liquid medium where the examination is performed outside the body." *Office Action of July 5, 2002, p. 2*. The Gumbrecht and Polanyi systems each have a catheter that is simply inserted into a patient's blood vessel. Gumbrecht and Polanyi fail to teach or suggest implanting a port body within a patient body wherein a portion of the port body extends through the skin.

Blanco fails to remedy the deficiencies of Gumbrecht and Polanyi. As pointed out above, Blanco teaches "[a]n implantable blood monitoring and medication administering system . . . which is implantable beneath the skin." *Blanco, Abstract*. Blanco does not teach or suggest implanting a port body within a patient body wherein a portion of the port body extends through the skin.

Since the references by themselves or in combination do not teach or suggest all aspects of independent claims 22, 23 and 40, the references do not make these claims obvious. Also, since dependent claims 24-39 and 41-45 incorporate the limitations of independent claims 23 and 40, respectively, the arguments presented above are equally applicable to the dependent claims. Therefore, the references by themselves or in combination do not make obvious the dependent claims 24-39 and 41-45.

CONCLUSION

The applicants have canceled claims 2-9, 11, and 19-21 and amended independent claims 22 and 23. The applicants have also added new claims 46-55.

In view of the preceding remarks and amendments, it is respectfully urged that the rejection of claims 22-45 be reconsidered and withdrawn, and that all the claims be allowed. However, if the Examiner believes that any issues remain unresolved, he is invited to telephone the undersigned to expedite allowance.

It is believed that there are no additional claim fees due as a result of the above amendments, but a petition to extend the time to respond by one month (from October 5, 2002 until November 5, 2002) is being submitted herewith, along with a check in the amount of \$110 to cover the fee associated with the petition. The Office is also hereby authorized to charge any fee deficiencies, or credit any overpayment, associated with this response or the petition to Deposit Account 04-1420.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Marked-up Version Showing Changes.**"

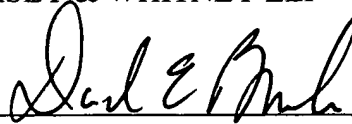
Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGES

IN THE CLAIMS

Please cancel claims 1-21.

Please amend the claims 22 and 23 as follows.

22. (Amended) A method for analyzing body fluids, in which a body fluid is accessed for analysis via an implantable means for accessing the fluid, said means comprising a port body implanted in [the] a patient's body, a portion of the port body extending through the skin, said port body comprising a tube arrangement extending into the interior of the body, wherein a test sensor is inserted into the interior of the body via said tube arrangement, and wherein a body fluid is analyzed by the sensor at an intermediate site of said tube arrangement, the body fluid being aspirated to said intermediate site.

23. (Amended) A method for analyzing body fluids comprising:
implanting a port body within a patient's body wherein a portion of the port body extends through the skin and the port body includes a first tube in contact with a source of body fluids;
aspirating the body fluids into the first tube; and
analyzing the body fluids.

Please add the following new claims 46-55.

46. (New) A method for analyzing body fluids, comprising the steps of:
implanting a port body in a patient's body, said port body extending through the skin of the patient's body and secured in place by an anchoring section located in or under the skin, said port body having a shaft with an elastic self-closing diaphragm therein and a tube arrangement extending into the interior of the patient's body from the self-closing diaphragm;
accessing body fluids through the implanted port body; and
analyzing the body fluids encountered at a test site within the patient's body.

47. (New) The method as set forth in claim 46, wherein the step of accessing body fluids further comprises the step of routing an aspiration catheter from a point outside the patient body, through the self-closing diaphragm and into the tube arrangement.

48. (New) The method as set forth in claim 47, wherein the aspiration catheter is used to withdraw a body fluid from the test site to a point outside the patient body, the body fluid then being analyzed at a remote location.

49. (New) The method as set forth in claim 47, wherein the aspiration catheter is used to aspirate a body fluid to the test site where a sensor or probe then encounters the body fluid.

50. (New) The method as set forth in claim 46, wherein the step of accessing body fluids further comprises the step of routing a probe from a point outside the patient body, through the self-closing diaphragm and into the tube arrangement.

51. (New) The method as set forth in claim 50, wherein the probe is a microdialysis probe.

52. (New) The method as set forth in claim 46, wherein the step of accessing body fluids further comprises the step of routing a sensor from a point outside the patient body, through the self-closing diaphragm and into the tube arrangement.

53. (New) The method as set forth in claim 52, wherein the shaft is made of a metallic material and acts as a reference or counter electrode for the sensor.

54. (New) The method as set forth in claim 52, wherein the sensor remains at the test site for continuous testing.

55. (New) The method as set forth in claim 52, wherein body fluid is aspirated to the test site, the sensor being located at the test site.